JUN - 5 2001

Medtronic Sofamor Danek
Biphasic Calcium Phosphate (BCP) Bone Void Filler (K010701)
Summary of Safety and Effectiveness
June 2001

I. **Company:** **Medtronic Sofamor Danek, Inc. USA**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

II. **Proposed Proprietary Trade Name:** Medtronic Sofamor Danek Biphasic Calcium Phosphate (BCP) Bone Void Filler

III. **Product Description**

The Medtronic Sofamor Danek BCP Bone Void Filler is made of medical grade biphasic calcium phosphate (BCP). The product is supplied sterile for single patient use. BCP granules undergo very slow resorption over a period of years when used according to labeling.

IV. **Indications**

Medtronic Sofamor Danek BCP Bone Void Filler is indicated for filling and contouring intraoral osseous defects such as periodontal lesions. BCP is also indicated to aid in the healing of periodontal wall defects, extraction socket defects, and for repair of cysts. BCP provides a bone void filler that resorbs and is replaced with bone during the healing process. BCP can be used with or without internal fixation

V. **Substantial Equivalence**

Documentation was provided which demonstrated the Medtronic Sofamor Danek BCP Bone Void Filler to be substantially equivalent to other previously cleared bone void fillers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2001

Mr. Richard W. Treharne
Senior Vice President of Regulatory Affairs
Medtronic Sofamor Danek USA, Incorporated
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K010701
Trade Name: Metronic Sofamor Danek Biphasic Calcium (BCP) Bone Void Filler
Regulatory Class: Unclassified
Product Code: LYC
Dated: March 6, 2001
Received: March 8, 2001

Dear Mr. Treharne:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010701

Device Name: Medtronic Sofamor Danek Biphasic Calcium Phosphate (BCP) Bone Void Filler

Indications for Use:

Medtronic Sofamor Danek BCP Bone Void Filler is indicated for filling and contouring intraoral osseous defects such as periodontal lesions. BCP is also indicated to aid in the healing of periodontal bone wall defects, extraction socket defects, and for repair of cysts. BCP provides a bone void filler that resorbs and is replaced with bone during the healing process. BCP can be used with or without internal fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-counter Use** _____
(Per 21 CFR 801.109)
(Optional 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010701